EMERGENCY USE AUTHORIZATION (EUA) SUMMARY

DSL COVID-19 Assay

(SARS-CoV-2 detection based on N1, N3, and S genes)

Diagnostic Solutions Laboratory, LLC

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

The DSL COVID-19 assay will be performed at the Diagnostic Solutions Laboratory, certified under the Clinical Laboratory Improvement Amendments of 1988(CLIA), 42 U.S.C. §263a to perform high complexity tests as per Laboratory Standard Operating Procedure that was reviewed by the FDA under this EUA.

INTENDED USE

The DSL-COVID19 assay is a RT-qPCR test intended for the qualitative detection of nucleic acid from the SARS-CoV-2 in upper respiratory specimens (such as nasal, mid-turbinate, nasopharyngeal, and oropharyngeal swabs) and bronchioalveolar lavage (BAL) specimens from patients suspected of COVID-19 by their healthcare provider. Testing is limited to Diagnostic Solutions Laboratory, LLC which is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, and meets requirements to perform high complexity tests.

Results are for the detection of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in upper respiratory specimens and BAL 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 positive 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.

The DSL COVID-19 assay is intended for use by clinical laboratory personnel specifically instructed and trained in the techniques of real-time RT-PCR assays and in vitro diagnostic procedures. The DSL COVID-19 assay is intended only for use under the Food and Drug Administration's Emergency Use Authorization.

DEVICE DESCRIPTION AND TEST PRINCIPLE

The DSL COVID-19 assay is a real-time reverse transcription polymerase chain reaction (rRT-PCR) test. The assay is for the presence of two coronavirus genes, the nucleocapsid and the spike gene. A total of three primer/probe sets were designed to detect nucleocapsid and spike RNA from the SARS-CoV-2 in upper respiratory specimens and BAL as recommended by public health authority guidelines. A total of two primer/probe sets (CDC's N1 and N3 primers) were designed to detect the viral nucleocapsid gene; 1) N1 is SARS-CoV-19 specific, 2) N3 is a coronavirus generic primer and probe set that can also detect other coronaviruses. The third primer/probe set was designed by Diagnostic Solutions Laboratory using the published SARS-CoV-2 reference genome to detect SARS-CoV-2 specific sequence of the *spike* gene. Blasting the spike primer and probe set indicated 100% homology with SARS-CoV-2 but no homology with any other nucleotide sequence present in the database, including both SARS-CoV (taxonomy ID 694009) and MERS-CoV (taxonomy ID 1335626). Each primer and probe sets are tested in individual reactions.

In addition, the test also detects the human RNase P gene as a sample internal extraction and amplification control using primers and probe sequences published by CDC. In addition, the test utilizes external controls as described below (low titer positive control and a negative control).

Upper respiratory specimens can be collected as dry swabs or as swabs in VTM. Dry swabs are eluted in 510µl of a PBS/proteinase K mix and digested at 56°C for 20 minutes. 200 µl of this swab eluate is used for RNA extraction. For wet swabs (i.e., swabs collected in VTM) and for BAL, 200µl of the VTM/BAL are used directly in the extraction. Nucleic acid from patient samples and internal RNase P control RNA (RNA-IC) molecules are simultaneously extracted using the Mag-Bind Viral DNA/RNA for RNA extraction and purification on the KingFisher Flex Purification System. This extraction method is based on well-established methods consistent with the Boom method. Selective amplification of target nucleic acid from the sample is achieved by reverse transcription of the SARS-CoV-2 RNA genome and subsequent RT-PCR run on the QuantStudio 5 Real-Time PCR System in a 384-well plate format.

INSTRUMENTS USED WITH TEST

The DSL COVID-19 assay is to be used with the following instruments:

1. KingFisher instrument for nucleic acid extraction with the Omega BioTek Mag-Bind Viral DNA/RNA 96 Kit extraction reagents
2. QuantStudio 5 Real-Time PCR System (QS5) with QS5 Analysis software for cDNA synthesis, PCR amplification of the target sequences and detection of amplicons.

EQUIPMENT, REAGENTS AND MATERIALS

The following equipment/reagents/materials are required to run this test:

Table 1: Reagents and Materials

Reagents	Manufacturer	Catalog #
Nucleic Acid Extraction Reagents		
Mag-Bind Viral DNA/RNA 96 Kit	Omega BioTek	M6246-03
KingFisher deep well plates, square wells with conical bottoms	ThermoFisher Scientific	95040450
KingFisher standard plate	ThermoFisher Scientific	97002540
200 proof ethanol, non-denatured	VWR	V1001
Phosphate Buffered Saline (PBS)	Corning	21-040-CM
100% Isopropanol	VWR	BDH1133-4LG
PCR Reagents		
Positive Control (SARS-Related Coronavirus 2, isolate USA-WA1/2020)	BEI Resources	NR-52285
SARS-CoV-2 TaqMan FAM/TAMRA PrimeTime qPCR Assays	Integrated DNA Technologies	DSL Custom IDs
qScript XLT One-Step RT-qPCR ToughMix, Low Rox	Quantabio	#95134
QuantStudio 5 Real-Time PCR System (QS5)	Applied Biosystems	A28139

CONTROLS TO BE USED WITH THE DSL COVID-19 ASSAY

- A Negative Template Control (NTC) serves as a negative process control to monitor for any reagent contamination and sample carryover that could occur during the extraction and amplification process. The NC consists of elution buffer and is run once for every batch of extracted specimens.

- A Positive Control (PC) is used to verify that the assay run is performing as intended. The PC is based on genomic RNA from SARS-Related Coronavirus 2 and will be positive for N1, N3, and S. The positive control is used once for each batch of extracted specimens.

- An Internal Control will be performed on every clinical sample as an endogenous control. The internal control is the human Ribonuclease P (RNase P) gene isolated with the sample RNA of each specimen. It will be used to confirm isolation efficiency as well as amplification.

INTERPRETATION 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.

a. Control Result Interpretation

Table 2: Expected Performance of Controls

Control Type	Control Name	N1	N3	S	IC	Expected Ct values
Negative Control	NTC	-	-	-	-	No Ct, or Ct > 39 for all targets
Positive Control	PC	+	+	+	-	< 35 Ct for N1, N3 and S
Internal Control	RNase P	-	-	-	+	Negative for N1, N3 and S; < 35 Ct for RNase P target.

If any of the above controls do not exhibit the expected performance as described, the assay may have been improperly set up and/or executed improperly, or reagent or equipment malfunction could have occurred. Invalidate the run and re-test.

b. Examination and Interpretation of Patient Specimen Results:

Assessment of clinical specimen 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.

COVID results of patient samples will be determined using the algorithm in Table 3 based on a Ct 39 cutoff: The Ct data are analyzed using the QuantStudio Analysis software v1.5.1. A fluorescent signal (Ct) ≤39 for any viral gene target will result in a positive result for that target. A fluorescent signal Ct >39 for any viral gene target will result in a negative result for that target.

Table 3. Interpretation of SARS-CoV-2 Specific Gene Data in Patient Samples

Interpretation	RNase P	SARS-CoV-2 N1	SARS-CoV-2 N3	SARS-CoV-2 spike	Action
COVID Negative	+	-	-	-	Report Result
COVID Positive	+	+	+	+	Report Result
	+	+	-	+	
	+	+	-	-	
	+	-	-	+	
	+	-	+	+	
	+	+	+	-	
COVID Inconclusive*	+	-	+	-	

Interpretation	RNase P	SARS-CoV-2 N1	SARS-CoV-2 N3	SARS-CoV-2 spike	Action
Repeat testing	**-**	**+/-**	**+/-**	**+/-**	

* For samples with a repeat inconclusive result, additional confirmatory testing may be conducted, if it is necessary to differentiate between SARS-CoV-2 and SARS-CoV-1 or other Sarbecoviruses currently unknown to infect humans, for epidemiological purposes or clinical management.

PERFORMANCE EVALUATION

1) Analytical Sensitivity:

SARS-CoV-2 viral stock USA-WA1/2020 (BEI Resources; NR-52281) with a stock concentration of $2x10^{10}$ genome copies (cp)/mL) was serially diluted in phosphate buffered saline to 10^{-1} cp/mL. 100µl of each viral concentration was used to inoculate dry NP swabs (FLOQSwabs, Copan) collected from individuals negative for SARS-CoV-2. Each concentration was tested in replicates as indicated; each replicate is one individual swab. Each swab was processes per laboratory SOP.

a. Tentative LoD – Dry Swab

The tentative LoD for the assays SARS-CoV-2 target sequences was determined using 10-fold serial dilutions with 3 replicates per dilution using known titers cp/mL) of the BEI viral stock SARS-CoV-2 USA-WA1/2020. Results are summarized in Table 4. The LoD was determined as the lowest concentration where ≥ 95% of the replicates were positive. Accordingly, the tentative LoD for DSL COVID-19 assay as per assay results interpretation is 10 cp/swab (**Table 4**).

Table 4: Tentative LoD (Dry Swab)

Target Level [cp/swab]	Valid Results	N1 Gene Positive			N3 Gene Positive			S Gene Positive			RNase P Positive		
		N	Mean Ct	Detection Rate	n	Mean Ct	Detection Rate	n	Mean Ct	Detection Rate	n	Mean Ct	Detection Rate
10^9	3	3	15.1	100%	3	15.2	100%	3	18.5	100%	3	26.1	100%
10^8	3	3	17.0	100%	3	18.1	100%	3	21.2	100%	3	23.7	100%
10^7	3	3	18.5	100%	3	20.6	100%	3	24.1	100%	3	23.5	100%
10^6	3	3	20.9	100%	3	23.4	100%	3	27.6	100%	3	24.2	100%
10^5	3	3	23.5	100%	3	26.9	100%	3	30.7	100%	3	24.2	100%
10^4	3	3	26.7	100%	3	30.1	100%	3	33.6	100%	3	22.8	100%
10^3	3	3	30.2	100%	3	33.2	100%	3	35.2	100%	3	24.0	100%
10^2	3	3	33.3	100%	3	36.5	100%	2	38.0	67%	3	24.5	100%
10^1	3	3	38.7	100%	3	38.3	100%	0	>40	0%	3	25.3	100%
10^0	3	0	>40	0%	0	>40	0%	0	>40	0%	3	25.6	100%
10^{-1}	3	0	>40	0%	0	>40	0%	0	>40	0%	3	23.2	100%
LoD: 10 cp/swab [lowest target level demonstrating >95% detection rate of SARS-CoV-2]													

b. Confirmatory LoD

To confirm the LoD, NP swabs collected from afebrile adults were inoculated with 100µl of a SARS-CoV-2 viral preparation at a concentration of 10^2 cp/mL (i.e., 10 copies/swab). Nucleic acids were then isolated according to manufacturer's protocol. Isolated nucleic acids were tested using the DSL COVID-19 assay. Results for each target are shown in Table 5. These data confirm that all samples spiked at the LoD of 10 copies/swab tested positive for both SARS-CoV-2 specific nucleocapsid (N1) and pan-specific CoV nucleocapsid (N3) but were negative for the SARS-CoV-2 spike. These data also confirm that the LoD of the DSL COVID-19 assay as per the assay result interpretation is 10 cp/swab.

Table 5. Confirmation of LoD (Dry Swab)

Target Level [cp/ swab]	Valid results	SARS-CoV-2 N1-Gene Positive			SARS-CoV-2 N3-Gene Positive			SARS-CoV-2 S-Gene Positive			RNase P Positive		
		n	Mean Ct	Detection Rate	n	Mean Ct	Detection Rate	n	Mean Ct	Detection Rate	n	Mean Ct	Detection Rate
10^1	20	20	37.5	100%	20	36.47	100%	0	>40	0%	20	28.1	100%

c. Tentative LoD - Wet Swab

To determine the LoD with wet swabs, a swab-system with 3 ml of viral transfer media was used. Swabs were obtained from SARS-CoV-2 negative individuals and the swabs were then inoculated with 100 µl of solutions containing different concentration of SARS-CoV-2 virus (BEI Resources). Swabs were then eluted in 3 mL VTM and extracted and tested according to the SOP using 200 µl VTM as input volume for the extraction. A reduced tentative LoD dilution series was run that indicated no change in LoD as compared with the dry swab LoD. RNA extraction Concentrations in Table 6 below are provided per swab.

Table 6. Tentative LoD with Swabs in 3 mL VTM

Target Level* [cp/swab]	Valid Results	SARS-CoV-2 N1 Gene Positive			CoV N3 Gene Positive			SARS-CoV-2 S Gene Positive			RNase P Positive		
		n	Mean Ct	Detection Rate	n	Mean Ct	Detection Rate	n	Mean Ct	Detection Rate	n	Mean Ct	Detection Rate
10^7	2	2	21.9	100%	2	23.6	100%	2	25.3	100%	2	27.15	100%
10^6	2	2	24.7	100%	2	27.0	100%	2	28.6	100%	2	28.78	100%
10^5	2	2	28.1	100%	2	30.5	100%	2	32.0	100%	2	26.55	100%
10^4	2	2	33.2	100%	2	34.6	100%	2	34.7	100%	2	28.71	100%
10^3	2	2	34.6	100%	2	35.9	100%	**2**	**37.5**	**100%**	**2**	29.97	100%
10^2	2	2	36.5	100%	2	36.3	100%	1	39.9	50%	2	26.15	100%
10^1	**2**	**2**	**38.7**	**100%**	**2**	**38.9**	**100%**	**0**	**>40**	**0%**	**2**	28.35	100%
10^0	2	0	>40	0%	0	>40	0%	0	>40	0%	2	28.40	100%
10^{-1}	2	0	>40	0%	0	>40	0%	0	>40	0%	2	29.77	100%
LoD: 10 cp/swab [lowest target level demonstrating >95% detection rate of SARS-CoV-2]													

d. Confirmatory LoD - Wet Swab

The tentative wet-swab LoD of 10 copies/swab was tested with 20 replicates to confirm the LoD. All replicates were individually processed per SOP. RNA extraction Concentrations in Table 7 below are provided per swab.

Table 7: Confirmatory LoD with Swabs in 3 mL VTM

Target Level [cp/swab]	Valid results	SARS-CoV-2 N1-Gene Positive			SARS-CoV-2 N3-Gene Positive			SARS-CoV-2 S-Gene Positive			RNase P Positive		
		n	Mean Ct	Detection Rate	n	Mean Ct	Detection Rate	n	Mean Ct	Detection Rate	n	Mean Ct	Detection Rate
10^1	20	20	37.6	100%	19	37.9	100%	2	38.6	10%	20	27.5	100%

2) ***Analytical Inclusivity/Specificity:***

a. Inclusivity

The DSL COVID-19 assay (N gene detection) utilizes primer and probe sets identical to the N1 and N3 primer/probe sequences used in the FDA authorized CDC 2019-Novel Coronavirus (2019-CoV) Real-Time RT-PCR Diagnostic Panel. Accordingly, an inclusivity analysis was not repeated for N1 and N3 targets.

For the *spike* gene 5146 full length SARS-CoV-2 sequences were screened. Sequences with poor sequence quality (i.e., sequences with undefined nucleotides marked by "N" in the sequences) and therefore, had less than 99% with the primer/probe set for the *spike* gene were excluded from the analysis. All full-length reference sequences contained in the database had 100% homology. In addition, a three-target assay design mitigates the occurrence of false negative results due to failure to amplify individual target sequences.

b. Cross-Reactivity

i. *In Silico* Analysis

The DSL COVID-19 assay (N gene detection) utilizes primer and probe sets identical to the N1 and N3 primer/probe sequences used in the FDA authorized CDC 2019-Novel Coronavirus (2019-CoV) Real-Time RT-PCR Diagnostic Panel. Accordingly, an *in silico* cross-reactivity analysis was not repeated for N1 and N3 targets.

The reference sequences of the organisms listed in Table 8 below were analyzed *in silico* for cross-reactivity with the SARS-CoV-2 *spike* gene primers and probe sequence of the DSL COVID-19 assay. The reference sequences were screened for homologue stretches of more than 5 consecutive nucleotides with the *spike* gene primers and probe sequences. For all organisms with sequence homology to the *spike*

gene primers or probe extending to more than 5 consecutive nucleotides the percentage of homology was provided calculated based on the total primer/probe length. Note that all sequences with less than 5 consecutive nucleotides of homology related to the *spike* gene primers and probes are denoted as "none" (no Homology) in the Table below.

The *spike* gene forward primer had greater than or equal to 50% homology with four non-coronavirus targets. The *spike* gene reverse primer only had homology with one non-SARS-CoV-2 coronavirus target. The *spike* gene probe only had homology to a single high priority bacterial target, *Streptococcus salivarius*. None of the homologies detected were significant and none of the sequences would result in an amplified product.

Table 8. Organisms assessed for *In Silico* Cross-Reactivity with the *Spike* Gene Primer/Probe Sequences

Organism	Reference Sequence	Forward Primer (24nt)	Reverse Primer (19nt)	Probe (25nt)
Human Coronavirus 229E	NC_002645.1	None	57.90%	None
Human Coronavirus OC43	NC_006213.1	None	None	<50%
Human Coronavirus HKU1	NC_006577.2	None	None	None
Human Coronavirus NL63	NC_005831.2	None	None	None
SARS-Coronavirus	NC_004718.3	None	None	None
MERS-Coronavirus	NC_019843.3	None	None	None
Adenovirus	KF268207.1	None	None	<50%
Human metapneumoniavirus (hMPV)	NC_039199.1	None	None	<50%
Parainfluenza virus 1-4	NC_003461.1, NC_003443.1, NC_001796.2, NC_021928.1	None	None	None
Influenza A	Multiple*	None	None	None
Influenza B	NC_000907.1	None	None	None
Enterovirus	NC_038308.1	None	None	None
Respiratory syncytial virus (RSV)	NC_001803.1	None	None	None
Epstein Barr Virus (EBV) HHV4	NC_009334.1	50%	None	None
Cytomegalovirus (CMV) HHV5	NC_006273.2	None	None	None
Rhinovirus (77/17/16)	FJ445154.1, EF173420.1, KX891411.1	None	None	None
Chlamydia pneumoniae	NC_000922.1	None	None	None
Haemophilus influenzae	NZ_LN831035.1	54.20%	None	None
Legionella pneumophila	NC_002942.5	None	None	None
M. tuberculosis	NC_000962.3	None	None	None
Streptococcus pneumoniae	NC_003098.1	50%	None	None

Organism	Reference Sequence	Forward Primer (24nt)	Reverse Primer (19nt)	Probe (25nt)
Streptococcus pyogenes	NC_002737.2	None	None	None
Bordetella pertussis	NC_018518.1	None	None	None
Mycoplasma pneumoniae	NC_000912.1	None	None	None
Pneumocystis jiroveci	LFWA01000001.1	None	None	None
Candida albicans	NC_032089.1	None	None	None
Pseudomonas aeruginosa	NC_002516.2	54.20%	None	None
Staphylococcus epidermis	NC_004461.1	None	None	<50%
Streptococcus salivarius	NZ_LR134274.1	None	None	60%

* Influenza A sequences: NC_007366.1, NC_007367.1, NC_007368.1, NC_007369.1, NC_007370.1, NC_007371.1, NC_007372.1, NC_007373.1

ii. Wet Testing

In addition to the *in silico* cross-reactivity, several high priority genomes were experimentally tested for cross-reactivity with the spike primers/probe set. Available bacterial and viral genomes were tested at a concentration of 10^6 CFU/mL or 10^6 PFU/mL in triplicate for reactivity. Data are shown in Table 9. As previously stated, the SARS-CoV-2 specific nucleocapsid (N1) and pan-specific CoV nucleocapsid (N3) are identical to the primer/probe sets tested by the CDC for the FDA authorized CDC EUA assay and thus, were not replicated in this study.

Table 9. Organisms Tested for Cross-Reactivity with the DSL COVID-19 Assay *Spike* Primer/Probe Set

	Target	Replicate 1	Replicate 2	Replicate 3
High Priority Pathogens from the same family (10^6 PFU/mL)				
Human Coronavirus 229E	Spike	Negative	Negative	Negative
Human Coronavirus OC43	Spike	Negative	Negative	Negative
Human Coronavirus NL63	Spike	Negative	Negative	Negative
High Priority, High Prevalence Respiratory Viruses (10^6 PFU/mL)				
Adenovirus	Spike	Negative	Negative	Negative
Cytomegalovirus (CMV)	Spike	Negative	Negative	Negative
Epstein Barr Virus (EBV)	Spike	Negative	Negative	Negative
Influenza A (H1N1)	Spike	Negative	Negative	Negative
Influenza B	Spike	Negative	Negative	Negative
Rhinovirus strain 16	Spike	Negative	Negative	Negative
Rhinovirus strain 17	Spike	Negative	Negative	Negative
Rhinovirus strain 77	Spike	Negative	Negative	Negative
High Priority Bacteria (10^6 CFU/mL)				
Mycobacterium tuberculosis	Spike	Negative	Negative	Negative
Streptococcus pyogenes	Spike	Negative	Negative	Negative
Candida albicans	Spike	Negative	Negative	Negative

Pseudomonas aeruginosa	Spike	Negative	Negative	Negative
Staphylococcus epidermis	Spike	Negative	Negative	Negative

The cross-reactivity data indicated that there was no cross-reactivity with any of the tested organisms at the concentration tested.

c. Microbial Interference

Microbial interference was tested with *P. aeruginosa* in the presence and absence of SARS-CoV-2. 20 negative NP swab samples were obtained and spiked with SARS-CoV-2 at 10 cp/swab. In addition, half of the swabs were spiked with 10^6 CFU/mL of *P. aeruginosa* while the other half was spiked with buffer (control). The swabs were processed according to the laboratory SOP.

Study data is summarized in Table 10 and indicates that the SARS-CoV-2 samples with *P. aeruginosa* have a mean Ct value that is 1 Ct lower that the Ct value of SARS-CoV-2 samples without *P. aeruginosa*. Ct values of the 10 samples without *P. aeruginosa* had a Standard Deviation (SD) of ±0.8 Ct. Because the Ct value in the presence of *P. aeruginosa* is lower than in the absence and the SD is almost 1 Ct value it was concluded that the presence of *P. aeruginosa* does not interfere with the detection of the SARS-CoV-2 *spike* gene and the difference in Ct is rather a consequence of random distribution of measurement error for low positive samples.

Table 10. Bacterial Inhibition of *Spike* Gene Detection by the Spike Primer/ Probe Set

P. aeruginosa	**Detected [n]**	**Mean Ct**	**Mean Difference [with *P. aeruginosa* - without *P. aeruginosa*] [Ct]**
-	10	38.1	-1.1
+	10	36.9	

3) <u>Clinical Evaluation:</u>

For clinical performance validation of the DSL COVID-19 assay, 64 dry clinical nasopharyngeal swab samples were tested with the DSL COVID-19 assay (32 positive samples and 32 negative samples) in comparison to an FDA EUA authorized SARS-CoV-2 PCR test with three targets (ORF1ab, S and N). Since the swabs were dry, and the extraction method for the authorized comparator and the investigational test were identical, samples were eluted and extracted once and then RT-PCR tested according to both, the instruction for use of the comparator assay and the SOP for the investigational test. Results of this comparison study are shown in Table 11. A single sample tested positive by the DSL COVID-19 assay and negative by the comparator test resulting in a negative percent agreement (NPA) of 97% and a positive percent agreement (PPA) of 100% between the two assays. The 95% confidence interval (CI)

was calculated based on the Wilson Score Method.

Note: Results are called "Inconclusive" when only one out of three targets is positive. These results were excluded because they are concordant for one the assays targets but discordant for the other target sequences in the test. Therefore, clinical truth cannot be established for these samples.

Table 11. Clinical Performance of DSL COVID-19 Assay with Nasopharyngeal Swabs

		FDA EUA Assay (ORF1ab, S, N)			
		Positive	Inconclusive	Negative	**Total**
Diagnostic Solutions Laboratories	Positive	29	2	1	32
	Inconclusive	0	0	0	0
	Negative	0	0	32	32
	Total	29	2	33	64

PPA: 29/29 = 100% (95% CI: 88.3% - 100%)
NPA: 32/33 = 97% (95% CI: 84.7% - 99.5%)

WARNINGS:

- For in vitro diagnostic use
- Rx only
- For use under Emergency Use Authorization (EUA) only
- This test has not been FDA cleared or approved;
- This test has been authorized by FDA under an EUA for use by the authorized laboratory;
- This test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and
- This test 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 Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.
- Positive results must be reported to country, state and local public health authorities as required.
- Handle all specimens as if infectious using safe laboratory procedures. Refer to Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with 2019-nCoV https://www.cdc.gov/coronavirus/2019-nCoV/lab-biosafety-guidelines.html.

LMITATIONS:

- The performance of this DSL COOVID-19 test was established using nasopharyngeal swabs specimens. Nasal, oropharyngeal and mid-turbinate swabs and BAL are also considered acceptable specimen types for use with the DSL COOVID-19 test.
- Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for treatment or other patient management decisions.
- A false negative result may occur if a specimen is improperly collected, transported or handled. False negative results may also occur if amplification inhibitors are present in the specimen or if inadequate numbers of organisms are present in the specimen.
- This test cannot rule out diseases caused by other bacterial or viral pathogens.
- Do not add bleach or acidic solutions directly to the sample preparation waste. Some sample collection devices contain guanidine isothiocyanate salt that can form cyanide gas when combined with bleach.