ACCELERATED EMERGENCY USE AUTHORIZATION (EUA) SUMMARY WARRIOR DIAGNOSTICS SARS-CoV-2 ASSAY

(The Warrior Diagnostics SARS-Cov-2 Assay will be performed at Warrior Diagnostics, Inc., a Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a certified high-complexity laboratory, per the Laboratory Standard Operating Procedure that was reviewed by the FDA under this EUA).

INTENDED USE

The Warrior Diagnostics SARS-CoV-2 Assay is a real-time *in vitro* diagnostic RT-PCR test intended for the qualitative detection of SARS-CoV-2 RNA in nasopharyngeal swabs, from individuals suspected of COVID-19 by their healthcare provider. Testing is limited to Warrior Diagnostics, Inc., that is a Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a certified high-complexity laboratory.

Results are for the detection and identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in respiratory specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all 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 Warrior Diagnostics SARS-CoV-2 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 assay is only for use under the Food and Drug Administration's Emergency Use Authorization.

DEVICE DESCRIPTION AND TEST PRINCIPLE

The Warrior Diagnostics SARS-CoV-2 assay is a real-time reverse transcription polymerase chain reaction (RT-PCR) test that is intended for use with nasopharyngeal swab samples from patients suspected of COVID-19 by their healthcare provider. The assay uses the same primers and probes as those in the FDA-authorized CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel (EUA200001) and is intended to amplify and detect two different regions of the SARS-CoV-2 nucleocapsid gene (N1 and N2), together with human RNase P nucleic acid as an endogenous internal control. Nucleic acid extraction is performed using the Invitrogen PureLink Viral RNA/DNA Mini Kit with an input volume of 200 µL and elution volume of 50 µL. PCR amplification is performed using the Agilent AriaMx Real-Time PCR System, with up to 30 patient samples and controls on each PCR plate.

INSTRUMENTS FOR USE WITH THE TEST

The COVID-19 test is to be used with the Agilent AriaMX running Aria software V1.5.

REAGENTS AND MATERIALS

Description	Supplier	Cat. #
PureLink Viral RNA/DNA Mini Kit	Invitrogen	12280050
SuperScript III Platinum One Step qRT-PCR kit	Invitrogen	11732020
2019-nCoV CDC EUA Kit	IDT	10006606
2019-nCoV_N Positive Control	IDT	10006625
AriaMx qPCR instrument with Aria 1.5 software	Agilent	G8830A
1.5mL Eppendorf tubes	Eppendorf	022431021
PCR Plate Cold Block	Eppendorf	022510525
PCR Plate	Agilent	401490
	Nest Scientific	402101
Optical caps or film	Agilent	401427
	Applied Biosystems	4311971
P10, P200, P1000 Pipettes with filter tips	N/A	N/A
BSL2-A2 certified hood with HEPA filter	N/A	N/A
WoWSwab	Warrior Diagnostics	WD0029

IDT: Integrated DNA Technologies

CONTROLS

Each PCR plate includes a no template Negative Control for each measurand (N1, N2 and RNase P), together with Positive Controls for detection of the N1 and N2 targets. The 2019-nCoV_N_Positive Control (IDT Cat. # 10006625) is used at a concentration of 450 copies/reaction. The Positive Control plasmid is also added to one amplification well for the RNase P target, although amplification/detection is not expected. All controls must produce the expected results in order to interpret the results from patient samples.

INTERPRETATION OF RESULTS

All Positive and Negative Controls must produce the expected results in order to interpret the results from patient samples (**Table 1**).

Table 1. Expected results from Positive and Negative Controls

Control	Measurand		
	N1	N2	RNase P
Positive	Positive	Positive	Negative
Negative	Negative	Negative	Negative

Positive: Cq < 38; Negative: Cq ≥ 38 or no Cq

If acceptable results for the Positive and Negative Controls are obtained, the results for patient sample are interpreted as shown in **Table 2**.

Table 2. Interpretation for patient results obtained with the Warrior Diagnostics SARS-CoV-2 Assay

Measurand			Interpretation	Report
N1	**N2**	**RNase P**		
Either or both Positive		Positive or Negative	SARS-CoV-2 Detected	Positive [1]
Negative	Negative	Positive	SARS-CoV-2 Not Detected	Negative [2]
Negative	Negative	Negative	Invalid	Invalid [3]

Positive: Cq < 38; Negative: Cq ≥ 38 or no Cq

[1] Report results to sender and appropriate public health authorities

[2] Report results to sender

[3] Retest once by re-extracting a new aliquot of the patient specimen and repeating the RT-PCR; if the result is again "Invalid", report to the sender and recommend collection of a new specimen if clinically indicated

PERFORMANCE EVALUATION

1) Analytical Sensitivity

Because SARS-CoV-2 RNA was not available at the time, the limit of detection (LoD) of the Warrior Diagnostics SARS-CoV-2 Assay was initially estimated using a plasmid clone of the N1 and N2 target regions (IDT Cat. #10006625) that was spiked into residual SARS-CoV-2 negative clinical matrix. The lowest level of plasmid DNA that was reliably detectable was determined to be approximately 150,000 copies/mL, with a mean Cq of approximately 34-36 for both the N1 and N2 targets.

To characterize the LoD further, additional testing was performed using dilutions of a known SARS-CoV-2 positive nasopharyngeal swab matrix. The results of the study demonstrated that at the LoD target level, the Warrior Diagnostics SARS-CoV-2 Assay produced Cq values of approximately 35 for both the N1 and N2 targets, which is consistent with the Cq values observed at the LoD target level with plasmid DNA.

Because the Clinical Evaluation of the Warrior Diagnostics SARS-CoV-2 Assay described in **Section H(2)** included extensive testing of clinical nasopharyngeal swabs in comparison to a previously FDA-authorized assay, additional characterization of the LoD was not performed.

2) Analytical Specificity

The target sequences for the Warrior Diagnostics SARS-CoV-2 Assay are the N1 and N2 regions of the viral nucleocapsid gene and the endogenous RNase P internal control from the FDA-authorized CDC 2019-Novel Coronavirus (2019-nCoV) Real-time rRT-PCR Panel (EUA200001). The inclusivity and analytical specificity of the CDC primers and probes were evaluated *in silico* at the time of FDA authorization. CDC has granted a right of reference to the performance data contained in the CDC's EUA request to any entity seeking an FDA EUA for a COVID-19 diagnostic device. Details of the *in silico* search results are contained in the Package Insert for the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-

PCR Diagnostic Panel. Additional evaluation of the inclusivity and potential for cross-reaction with the Warrior Diagnostics SARS-CoV-2 Assay was not performed.

3) Clinical Evaluation

The performance of the Warrior Diagnostics SARS-CoV-2 Assay was evaluated using known SARS-CoV-2 positive and negative nasopharyngeal swab specimens that had previously been characterized using the FDA-authorized COVID-19 RT-PCR test developed by the Laboratory Corporation of America (LabCorp).

As determined by the LabCorp comparator assay, a total of 31 SARS-CoV-2 positive and 29 SARS-CoV-2 negative nasopharyngeal specimens were included in the study. Both the comparator and the Warrior Diagnostics assays were performed in triplicate. There was 100% concordance between replicates of the comparator assay. The results from replicates 1, 2 and 3 from the Warrior Diagnostics SARS-CoV-2 assay are presented separately in **Table 3**, as well as with all results combined. There was 100% positive agreement with the comparator for all three replicates of the Warrior Diagnostics SARS-CoV-2 Assay. One replicate of one sample that was SARS-CoV-2 negative by the comparator gave an unexpected positive result for the N1 target in the Warrior Diagnostics assay and therefore negative percent agreement ranged from 96.6 to 100%, depending on the assay replicate.

Table 3. Performance of the Warrior Diagnostics SARS-CoV-2 Assay in comparison to the LabCorp COVID-19 RT-PCR test

		Comparator		
		Positive	**Negative**	**Total**
Warrior Diagnostics Replicate 1	**Positive**	31	1	**32**
	Negative	0	28	**28**
	Total	**31**	**29**	**60**
Positive Agreement		**100% (31/31); 89.0-100%** [1]		
Negative Agreement		**96.6% (28/29); 82.8-99.4%**		

		Comparator		
		Positive	**Negative**	**Total**
Warrior Diagnostics Replicate 2	**Positive**	31	0	**31**
	Negative	0	29	**29**
	Total	**31**	**29**	**60**
Positive Agreement		**100% (31/31); 89.0-100%**		
Negative Agreement		**100% (29/29); 88.3-100%**		

		Comparator		
		Positive	**Negative**	**Total**
Warrior Diagnostics Replicate 3	**Positive**	31	0	**31**
	Negative	0	29	**29**
	Total	**31**	**29**	**60**
Positive Agreement		**100% (31/31); 89.0-100%**		
Negative Agreement		**100% (29/29); 88.3-100%**		

		Comparator		
		Positive	**Negative**	**Total**
Warrior Diagnostics Overall [2]	**Positive**	93	1	**94**
	Negative	0	86	**86**
	Total	**93**	**87**	**180**
Positive Agreement		**100% (93/93); 96.0-100%**		
Negative Agreement		**98.9% (86/87); 93.8-99.8%**		

[1] Two-sided 95% score confidence interval

[2] All replicates combined (total 31 discrete samples with 3 assay replicates each)

Both the comparator LabCorp device and the Warrior Diagnostics SARS-CoV-2 Assay use the same CDC primer and probe sequences for detection of the N1 and N2 target regions of the viral genome. A comparison of the results obtained for each region is shown in **Table 4**. There was acceptable agreement between the two assays for each target. There was also good correlation between Cq values for both the N1 and N2 targets across the dynamic ranges of both assays ($R^2 > 0.95$; data not shown).

Table 4. Comparison of results obtained with the Warrior Diagnostics SARS-CoV-2 Assay and LabCorp comparator assay with SARS-COV-2 positive samples, stratified by target region

Assay	Replicate	Positive (%)		
		N1 Only	N2 Only	N1 and N2
Comparator	1	0	0	31 (100)
	2	0	0	31 (100)
	3	0	0	31 (100)
Warrior Diagnostics	1	1 (3.2)	1 (3.2)	29 (93.5)
	2	1 (3.2)	0	30 (96.8)
	3	0	0	31 (100)

Note: Based on the result algorithm for the Warrior Diagnostics SARS-CoV-2 Assay depicted in **Table 2**, if either the N1 or N2 target is positive (Cq < 38), the sample should be reported as "Positive for SARS-CoV-2."

WARNINGS:

- This test has not been FDA cleared or approved;
- This test has been authorized by FDA under an EUA for use by authorized laboratories;
- This test has been authorized only for the detection of nucleic acid from SARSCoV-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.