

**EMERGENCY USE AUTHORIZATION (EUA) SUMMARY  
TEXAS DEPARTMENT OF STATE HEALTH SERVICES (DSHS)  
SARS-CoV-2 ASSAY  
(TEXAS DEPARTMENT OF STATE HEALTH SERVICES,  
LABORATORY SERVICES SECTION)**

**Texas Department of State Health Services (DSHS) SARS-CoV-2 Assay**

For *in vitro* Diagnostic Use  
Rx Only

For Use Under Emergency Use Authorization (EUA) Only

**(The Texas Department of State Health Services (DSHS) SARS-CoV-2 Assay will be performed at the Texas Department of State Health Services, Laboratory Services Section, located at 1100 W. 49<sup>th</sup> Street, Austin, TX 78756, 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, as described in the Laboratory Standard Operating Procedures that were reviewed by the FDA under this EUA).**

**INTENDED USE**

The Texas Department of State Health Services (DSHS) SARS-CoV-2 Assay is a real-time RT-PCR test intended for the qualitative detection of nucleic acid from the SARS-CoV-2 in nasopharyngeal swabs, oropharyngeal (throat) swabs, anterior nasal swabs, mid-turbinate nasal swabs, nasal aspirates, nasal washes and bronchoalveolar lavage (BAL) fluid specimens from individuals suspected of COVID-19 by their healthcare provider. Testing is limited to the Texas Department of State Health Services, Laboratory Services Section located at 1100 W. 49<sup>th</sup> Street, Austin, TX 78756, which is certified under 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 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 infected 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 test results to the appropriate public health authorities.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

The Texas Department of State Health Services (DSHS) SARS-CoV-2 Assay is intended for use by qualified clinical laboratory personnel specifically instructed and trained in the techniques of real-time PCR assays and *in vitro* diagnostic procedures. The Texas Department of State Health Services (DSHS) SARS-CoV-2 Assay is only for use under the Food and Drug Administration's Emergency Use Authorization.

## DEVICE DESCRIPTION AND TEST PRINCIPLE

The Texas DSHS SARS-CoV-2 Assay is a real-time reverse transcription polymerase chain reaction (rRT-PCR) test. The assay uses primers and probes that were developed and validated under the Emergency Use Authorization (EUA) for the PerkinElmer New Coronavirus Nucleic Acid Detection Kit and which are designed to detect RNA from the SARS-CoV-2 nucleocapsid (N) gene and ORF1ab. The assay is for use with respiratory specimens from patients suspected of COVID-19 by their healthcare provider.

## INSTRUMENTS USED WITH THE TEST

The Texas DSHS SARS-CoV-2 Assay is to be used with the PerkinElmer Chemagic 360 (software version 6.3.0.3) and ThermoFisher Applied Biosystems 7500 Fast Dx Real-Time PCR System (software version 1.4). Optionally, the PerkinElmer Janus G3 Automated Workstation (Janus Application Assistant software version 5.5.48.0) can be used to automate the process of aliquoting prepared PCR mix to a 96-well PCR plate and then adding extracted nucleic acid into the same plate containing PCR mix.

## REAGENTS AND MATERIALS

Reagent	Catalogue Number	Storage Temperature
Chemagic Viral DNA/RNA 300 Kit H96	PerkinElmer CMG-1033-S or equivalent	15 to 25 °C
New Coronavirus Nucleic Acid Detection Kit	PerkinElmer 2019-nCoV-PCR-AUS or equivalent	-15 to -25 °C
70% ethanol	--	--
RNase Away or equivalent	--	--
Milli-Q Type I Ultrapure Water	--	15 to 25 °C

Equipment and Supplies
Perkin Elmer Chemagic 360 (equipped with software V6.3.0.3)
Biosafety Cabinet (hood)
Sterile pipettes
3 mL Conical Tube
Sharps container
Biohazard waste box (UN3291)
Micropipettors (0.5-10 µL, 10-100 µL, 50-200 µL, and 100-1000 µL)
Multichannel micropipettes (10-100 µL, 30-300 µL, 50-1200 µL)
Troughs
Water bath
Disposable powder-free gloves, surgical gowns
Vortex mixer
Nuclease-free pipette tips
RNase/DNase-free 1.5 ml polypropylene microcentrifuge tubes
Chemagic Viral DNA/RNA 300 Kit required plastic consumables:

<b>Equipment and Supplies</b>
<ul style="list-style-type: none"> <li>• Chemagic Disposable Tip plate</li> <li>• Chemagic Low-well plate</li> <li>• Chemagic Deep-well plate</li> </ul>
Cold Block/Tray with ice bath
Racks for 1.5 mL, 0.5 mL microcentrifuge tubes
Reagent cold blocks
Rack for sample vials
Benchtop Microcentrifuge
Personal Protective Equipment (PPE)
Sealable isolator carrying case
Disposable/reusable plate seals
-70 °C and -20 °C Freezers
4 °C refrigerator
96-well Plate Centrifuge, refrigerated
96-well cold blocks
Water bath
PerkinElmer Janus G3 Workstation equipped with Janus Application Assistant software V5.5.48.0
175 µL conductive filter tips, sterile (PerkinElmer Cat. #6000687)
1.5/2 mL Cooling Tube Holder Set (PerkinElmer Cat. #6001310)
Janus 96-Well Magnet (PerkinElmer Cat. #7002416)
Applied Biosystems 7500 Fast Dx Real-time PCR Instrument with SDSSoftware V1.4
Applied Biosystems MicroAmp Fast Optical 96-Well reaction Plate with Barcode, 0.1 mL (Thermo Fisher Cat. #4346906 or #4366932)
Applied Biosystems Microamp Optical Adhesive Film Covers (Thermo Fisher Cat. #4311971)
Applied Biosystems MicroAmp Optical 8-cap Strip (Thermo Fisher Cat. #4323032)
Sealable, leak-proof carry case

## CONTROLS

The PerkinElmer New Coronavirus Nucleic Acid Detection Kit includes the following control materials:

- a) nCoV Positive Control:
  - Comprised of SARS-CoV-2 RNA fragments capsulated in a bacteriophage coat.
  - Used to monitor the adequacy of nucleic acid extraction and integrity of the RT-PCR reagents and process. Tested in parallel with every batch of patient samples.
  
- b) nCoV Negative Control:
  - Comprised of Tris-EDTA (TE) buffer.
  - Used to monitor for cross-contamination during the nucleic acid extraction and RT-PCR process. Tested in parallel with every batch of patient samples.

- c) nCov Internal Control:  
 Comprised of bacteriophage MS2 in TE buffer.  
 Used to monitor nucleic acid extraction, reverse transcription, PCR amplification and fluorescence detection. Added to each patient sample and control prior to nucleic acid extraction.

In addition to the controls provided with the assay kit, a No Template Control containing none of the SARS-CoV-2 targets or the Internal Control is included in every PCR run.

## INTERPRETATION OF RESULTS

The results from the controls are interpreted according to the criteria shown in **Table 1**

**1.** If the results obtained with the Positive, Negative and No Template Controls do not meet the criteria shown, the results from the entire batch of samples are considered invalid and repeat testing must be performed.

**Table 1.** Acceptable RT-PCR results for controls

Control Type	Acceptable Ct Value		
	N Gene (FAM)	ORF1ab (ROX)	Internal Control (VIC)
Negative	Undetermined or > 42	Undetermined or > 42	Ct ≤ 40
Positive	≤ 35	≤ 35	~ <sup>1</sup>
No Template	Undetermined or > 42	Undetermined or > 42	Undetermined or > 40

<sup>1</sup> No requirements on Ct value

The results from testing of patient samples are interpreted according to the criteria described in **Table 2**.

**Table 2.** Summary of results interpretation for patient samples

Ct Value			Interpretation
N Gene (FAM)	ORF1ab (ROX)	Internal Control (VIC)	
Both Undetermined or > 42		≤ 40	SARS-CoV-2 not detected
Either or both targets ≤ 42		~ <sup>1</sup>	SARS-CoV-2 detected
Both Undetermined or > 42		> 40 or Undetermined	Invalid <sup>2</sup>

<sup>1</sup> No requirements on Ct value

<sup>2</sup> Specimen needs to be re-tested by re-extracting nucleic acid or collection of a new sample

## PERFORMANCE EVALUATION

All PCR plates for the validation studies were set up using PerkinElmer Janus G3 Automated Workstation.

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

The Limit of Detection (LoD) of the Texas DSHS SARS-CoV-2 Assay was determined by testing dilutions of the PerkinElmer nCoV Positive Control bacteriophage that is provided within the assay kit. The LoD was initially estimated by testing three different concentrations of the control in Viral Transport Medium (VTM), Liquid Amies Medium and sterile saline (**Table 3**). The lowest concentration at which all three replicates produced positive results for both the N gene and ORF1ab was 20 copies/mL. This estimated LoD was then confirmed by testing a further 20 replicates in each transport medium. The LoD of the Texas DSHS SARS-CoV-2 Assay was confirmed to be 20 copies of the Positive Control bacteriophage/mL medium. No difference in analytical sensitivity was observed between the different types of transport medium.

**Table 3.** Estimation of the Texas DSHS SARS-CoV-2 Assay LoD

Transport Medium	Copies/mL	N Gene		ORF1ab	
		Positive (%)	Mean Ct (SD)	Positive (%)	Mean Ct (SD)
VTM	7	3/3 (100)	35.8 (0.36)	2/3 (67) <sup>1</sup>	36.7 (0.74)
	20	3/3 (100)	34.9 (0.50)	3/3 (100)	35.8 (0.28)
	60	3/3 (100)	33.5 (0.27)	3/3 (100)	35.1 (0.19)
Liquid Amies Medium	7	3/3 (100)	35.6 (0.55)	3/3 (100)	33.5 (0.39)
	20	3/3 (100)	34.7 (0.63)	3/3 (100)	32.8 (0.80)
	60	3/3 (100)	33.1 (0.07)	3/3 (100)	31.7 (0.35)
Sterile Saline	7	2/3 (67) <sup>1</sup>	37.2 (1.45)	3/3 (100)	34.2 (0.43)
	20	3/3 (100)	35.0 (0.10)	3/3 (100)	33.2 (0.17)
	60	3/3 (100)	33.2 (0.41)	3/3 (100)	32.1 (0.36)

SD: Standard Deviation; VTM: Viral Transport Medium

<sup>1</sup> 1/3 samples gave a result of “Undetermined” for this analyte; however, based on the result algorithm and detection of the other SARS-CoV-2 target, the sample was still reported as “Positive for SARS-CoV-2”

**Table 4.** Confirmation of the Texas DSHS SARS-CoV-2 Assay LoD

Transport Medium	Copies/mL	N Gene		ORF1ab	
		Positive (%)	Mean Ct (SD)	Positive (%)	Mean Ct (SD)
VTM	20	20/20 (100)	34.6 (0.68)	20/20 (100)	32.9 (0.62)
Liquid Amies Medium	20	20/20 (100)	34.6 (0.47)	20/20 (100)	32.6 (0.66)
Sterile Saline	20	20/20 (100)	35.1 (1.29)	20/20 (100)	33.5 (1.17)

**2) Inclusivity (Analytical Sensitivity):**

The Texas DSHS SARS CoV-2 Assay is a modification of the previously authorized PerkinElmer New Coronavirus Nucleic Acid Detection Kit. The assay targets specific genomic regions of the SARS-CoV-2 nucleocapsid (N) gene and ORF1ab region.

Texas DSHS has obtained a Right of Reference from PerkinElmer to the analytical sensitivity and specificity data and associated summaries included in the original EUA request for the New Coronavirus Nucleic Acid Detection Kit. As a result, Texas DSHS did not perform any additional analysis of the inclusivity or specificity of the New Coronavirus Nucleic Acid Detection Kit primers and probes.

**3) Cross-reactivity (Analytical Specificity)**

As noted above, the Texas DSHS SARS CoV-2 Assay is a modification of the previously authorized PerkinElmer New Coronavirus Nucleic Acid Detection Kit ([EUA200055](#)), and Texas DSHS has obtained a Right of Reference to the analysis of specificity performed in support of PerkinElmer’s original EUA request. The specificity of the PerkinElmer assay was demonstrated through a combination of *in silico* analysis of nucleic acid sequences for common respiratory pathogens/flora and laboratory testing. No cross-reactivity with the human genome, other coronaviruses, or human microbial flora was predicted or observed.

**4) Clinical Evaluation:**

*Evaluation of Clinical Specimens*

Testing was performed using a total of 47 natural clinical specimens of known SARS-CoV-2 status, as determined using an EUA-authorized molecular comparator assay (**Table 5**). There was 100% positive and negative percent agreement between the two assays.

**Table 5.** Cumulative results from testing prospectively collected and retrospective natural clinical specimens with the Texas DSHS SARS-CoV-2 Assay

		EUA-authorized comparator		
		Positive	Negative	Total
Texas DSHS SARS-CoV-2 Assay	Positive	30 <sup>+</sup>	0	30
	Negative	0	45	45
	Total	30	45	75
Positive Agreement		100% (30/30); 88.7-100%		
Negative Agreement		100% (45/45); 92.1-100%		

**WARNINGS**

- Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner.
- For prescription use only.
- For *in vitro* diagnostic use.
- 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 Texas Department of State Health Services, Laboratory Services Section, located at 1100 W. 49<sup>th</sup> Street,

Austin, TX 78756.

- This test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.
- This test 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 Cosmetics Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

**LIMITATIONS**

- The performance of this test was established based on the evaluation of a limited number of clinical specimens. Clinical performance has not been established with all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.

**FDA SARS-CoV-2 Reference Panel Testing**

The evaluation of sensitivity and MERS-CoV cross-reactivity was performed using reference material (T1), blinded samples and a standard protocol provided by the FDA. The study included a range finding study and a confirmatory study for LoD. Blinded sample testing was used to establish specificity and to confirm the LoD. The extraction was automated using the PerkinElmer Chemagic 360 (software version 6.3.0.3) and the amplification was run on the ThermoFisher Applied Biosystems 7500 Fast Dx Real-Time PCR System. The results are summarized in the following Table.

**Table 10.** Summary of LoD Confirmation Result using the FDA SARS-CoV-2 Reference Panel

<b>Reference Materials Provided by FDA</b>	<b>Specimen Type</b>	<b>Product LoD</b>	<b>Cross-Reactivity</b>
SARS-CoV-2	Nasopharyngeal	1.8x10 <sup>3</sup> NDU/mL	N/A
MERS-CoV	Swabs in VTM	N/A	ND

NDU/mL = RNA NAAT detectable units/mL

N/A: Not applicable

ND: Not Detected